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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,796	12/14/2001	Erhard Mueller	24857	1639
7590 03/18/2004 NATH & ASSOCIATES PLLC 1030 15TH Street NW - 6th Floor Washington, DC 20005			EXAMINER GRAY, JILL M	
			ART UNIT 1774	PAPER NUMBER

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/014,796

Applicant(s)

MUELLER ET AL.

Examiner

Jill M. Gray

Art Unit

1774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/27/02, 5/22/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

Claims 7, 9 and 22 are objected to because of the following informalities: In claim 7, line 3 the word "of" is omitted. In claim 9, line 1 "on" should be "one". Claim 22, line 1, the word "the" is omitted. Appropriate correction is required.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on December 16, 2000. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

### ***Information Disclosure Statement***

The non-initialed references were not considered because no copy has been provided.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 8, 10, 12-21 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More specifically, in claim 1, the language of "comprising one or more filaments and formed with a coating" is indefinite because it is not clear whether this language refers to coated filaments per se, or a process of making the filaments.

In claim 6, the language of "in the range of more than 30,000 Daltons" is indefinite because no range is specified. The suggested language is "molecular weight of more than 30,000 Daltons".

As to claim 8, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation inherent viscosity of 0.4 to 3.0 dl/g, and the claim also recites "particularly 0.7 to 1.3 dl/g" which is the narrower statement of the range/limitation.

In claim 10, the language of "formed from a combination of the bioresorbable polymer with fatty acid salts" is vague and indefinite because the term "combination" is non-specific and can describe mixed, blended, grafted or polymerized.

As to claim 12, this claim is generally narrative and indefinite, failing to conform with current U.S. practice.

Claim 13 is vague and indefinite and is drawn to the future processing of the terpolymer. Also, this claim does not provide a positive recitation of the terpolymer properties.

In claim 14, line 1, the word "it" is vague and indefinite because it is not clear whether this term refers to the terpolymer or suture material. Also, the language of "formed from a combination of the bioresorbable polymer with fatty acid salts" is vague and indefinite because the term "combination" is non-specific and can describe mixed, blended, grafted or polymerized.

Claim 15 is vague and indefinite for the reasons stated above.

Claim 16 is indefinite because this claim is generally narrative and indefinite, failing to conform with current U.S. practice. Also, the language of "wherein the coating takes place by the application of a bioresorbable polymer" is vague because it does not provide a clear recitation of process steps that define how this application takes place, what is applied and the substrate that receives the applied material.

Claim 17 is indefinite because this claim is generally narrative and indefinite, failing to conform with current U.S. practice.

As to claim 18, this claim is indefinite because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is

followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 18 recites the broad recitation a concentration of 0.1 to 10, and the claim also recites 0.5 to 5 wt.% which is the narrower statement of the range/limitation. Also, the range 0.1 to 10 does not have units of measurements. The suggested range is 0.1 to 10 wt. %.

Claims 19-21 are indefinite because these claims are generally narrative in form, failing to conform with current U.S. practice. The language that renders these claims narrative is "wherein for coating purposes".

Claim 24 is indefinite because this claim is generally narrative in form and fails to conform with current U.S. practice. In particular, this claim does not provide a positive recitation of a process step wherein the terpolymer is melted.

Claim 25 is vague and indefinite because it is not clear whether the term "coating" in line 1 refers to the coating process or coating solution. Also, the language of "formed from a combination of the bioresorbable polymer with fatty acid salts" is vague and indefinite because the term "combination" is non-specific and can describe mixed, blended, grafted or polymerized.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 14 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al, 4,705,820 (Wang).

Wang teaches a coating material for surgical sutures formed from a bioresorbable random terpolymer having an amorphous structure and a process for producing said suture wherein said terpolymer contains fatty acid salts and is dissolved in an organic solvent when applied to the substrate, as required by claims 12, 14 and 16-17. See abstract, column 1, lines 5-13, column 3, line 6, and lines 50-53 and Example 8.

Therefore, the teachings of Wang anticipate the invention as claimed in present claims 12, 14 and 16-17.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-11, 13, 15, 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al, 4,708,820 (Wang) in view of Bezwada et al, 5,371,176 and 4,994,074 (Bezwada).

Wang teaches a surgical suture coating comprising an amorphous bioresorbable random copolymer, said copolymer comprising glycolide and trimethylene carbonate, that can be present in amounts within applicants' range, further teaching that his polymer can contain other monomers such as caprolactone, as required by claims 1, 4 and 5. See abstract, column 1, line 5-9 and column 3, lines 6-7. Wang does not specify the amount of said monomers that can be added. In addition, Wang teaches that his coating has an inherent viscosity of from 0.5 to 3 dl/g and a glass transition temperature of less than about 25°C, as required by claims 7 and 8. See column 2, lines 3-37. The coating of Wang can contain a plasticizer and fatty acid salts, per claims 9-10, 14-15 and 25, although silent as to the specific amount of plasticizers. See column 3, lines 45-51 and Example 8. Regarding claim 6, Wang does not teach specific molecular weight amounts of his polymer. However, he does teach that his polymer has a relatively high molecular weight in order to have a reasonable tensile strength. Note column 3, line 29-35. Accordingly, it is the examiner's position that this teaching of Wang renders obvious the requirement of claim 6 of an average molecular weight in the range of more than 30,000 Daltons. The skilled artisan would have been reasonably motivated to use higher molecular weight polymers in order to have relatively good tensile strength. As to claims 18 and 24, Wang teaches a process for coating a suture material wherein the polymer is incorporated in a concentration within applicants' range and dried. See Example 8.

Bezwada '176 teaches an absorbable polymer for use as a coating for surgical sutures comprising about 50-90 parts by weight of lactone monomers such as e-



caprolactone and trimethylene carbonate and about 90-10 parts by weight of glycolide, wherein a mixture of lactones can be used. See abstract, and column 3, line 56 through column 4, and line 17. The polymer can also contain fatty acid salts, as set forth by applicants in claims 10, 14-15, and 25, and a plasticizer in an amount ranging from 0.5 to about 30 parts by weight, per claim 9. See column 5, lines 5-15. In addition, Bezwada '176 teaches that the coating can be applied to the surface of the suture in an amount ranging from about 0.5 to about 30 percent of the weight of the coated suture, as required by claim 11. See column 6, lines 30-42.

As set forth previously, Wang teaches that his polymer comprises glycolide and trimethylene carbonate and can comprise monomers such as caprolactone, although silent as to the specific amount of caprolactone. It would have been obvious to form a composition as taught by Wang wherein caprolactone is included, thereby using a mixture of soft monomers as taught by Bezwada '176. Furthermore, the teachings of Bezwada '176 would have provided motivation to the skilled artisan to use said mixture in the composition of Wang in amounts within the range of 10 to 50 parts by weight, (which necessarily obviate applicants' range of claim 1 and ratio of claim 4) in order to obtain a coating that is compatible with conventional solvents and aids in providing a lowered melting temperature and glass transition temperature.

As to claim 9, the teachings of Bezwada '176 of using a plasticizer in amounts within applicants' range would have provided direction to the skilled artisan at the time the invention was made to modify the composition of Wang by including 1 to 30 wt% of a plasticizer in order to enhance the performance of the polymer. Furthermore, the

teachings of Bezwada '176 would have provided a suggestion and motivation to the skilled artisan to coat the composition of Wang onto suture material such that the coating represents 0.5 to about 30wt% of the total weight of the coated suture material, as contemplated by applicants in claim 11 to result in a coated suture that is slippery and easy to manipulate without increasing the risk of the coating flaking off.

As to claims 19-23, Bezwada '176 teaches a process for producing suture material wherein a suture material is dipped in a coating solution containing organic solvents and cured in an oven at 100°-200°C (Example 8) and Bezwada '074 teaches that "once a solution of the copolymer is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc." (column 3, lines 47-51). The teaching of Bezwada '176 would have provided direction and a suggestion to the skilled artisan at the time the invention was made to modify the process as taught by Wang, wherein after coating, the suture material is dried with a heating device at a temperature within applicants' range as set forth in claim 23 with the reasonable expectation of removing the solvent. In addition, the teachings of Bezwada '074 would have provided a suggestion to the skilled artisan that any conventional coating techniques known in the art such as those contemplated by applicants in claims 19-21 could be used in the process of Wang with the reasonable expectation of success of obtaining coated suture material. As to claim 22, this requirement is no more than what would be considered in the room temperature range. It would have been obvious to perform the coating process within the room temperature range in the absence of clear factual evidence to the contrary.

Therefore, the combined teachings of Wang and Bezwada '176 and '074 would have rendered obvious the invention as claimed in present claims 1, 4-11, 13, 15, and 18-25.

No claims are allowed.


### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill M. Gray whose telephone number is 571-272-1524. The examiner can normally be reached on M-F 10:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cynthia Kelly can be reached on 571-272-1526. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jill M. Gray  
Examiner  
Art Unit 1774